



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/695,178 | 10/28/2003 | J. Daniel Raulerson | MED0065 | 4287 |
| 33941 | 7590 | 12/29/2009 | EXAMINER | |
| Fox Rothschild LLP Blue Bell 2000 Market Street Tenth Floor Philadelphia, PA 19103 | | | VU, QUYNH-NHU HOANG | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/29/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

| | | |
|--------------------------------------|---|--|
| Application No. 10/695,178 | Applicant(s) RAULERSON ET AL. | |
| Examiner QUYNH-NHU H. VU | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 November 2009.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 34-38 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 34-38 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

Art Unit: 3763

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 07/24/09 have been entered.

Claims 34-38 are present for examination.

Claims 1-33 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being obvious over Sisley et al. (US 4,405,313).

Sisley discloses a multiple catheter assembly, comprising:

a first catheter 12 having a first distal end region and a first proximal end region joined by a first intermediate section;

a second catheter 14 having a second distal end region and a second proximal end region joined by a second intermediate section;

first and second extension tube assemblies 24 and 26 having first and second distal end portions respectively associated with the first and second proximal end regions of the first and second catheters; and

a hub member/splitter 22 is capable/adapted to be releasably attachable to and around the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof, after catheter implantation and subcutaneous tunneling and at a site along the first and second proximal end region selectable by the practitioner, such that portions of the proximal end regions of the first and second catheters extend through the hub member 22 and proximally beyond the proximal end of the hub

Art Unit: 3763

member, to be connected to respective one of the first and second extension tube assemblies. See Figs. 1 & 4.

It has been held that the recitation that the hub member is "adapted to/capable of" and the limitation "after catheter implantation and subcutaneous tunneling" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. In this case, the hub member/splitter 22 does not show in Fig. 4 during or after catheter implantation and subcutaneous tunneling. Therefore, the hub member/splitter 22 is capable of releasable and attachable to and around the first and second proximal end region of the first and second catheters. Beside that, the hub member is releasable and attachable to catheters is very well-known in the catheter art.

Regarding claim 35, wherein the cross section shapes of the first and second proximal end region is circular; and the cross section shapes of the first and second distal end portions of the first and second extension tube is circular, see Figs. 1-3.

Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley et al. in view of Ash (US 5,947,953)

Sisley discloses all claimed subject matter except for that the cross sectional shapes of the first and second intermediate sections of the first and second catheters is circular but not a semicircular, as requires in claim 36

Ash discloses a similar catheter device comprising: the cross sectional shapes of the first and second intermediate sections of the first and second catheters is semicircular, see Fig. 4F; and the first and second catheters have transition sections between the circular cross-sectional shapes of the first and second proximal end and distal end regions and the semicircular cross-sectional shapes of the first and second intermediate sections, see Figs. 1-4G.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Sisley with the semicircular cross sectional shapes of the first and

Art Unit: 3763

second intermediate sections of the first and second catheter, as taught by Ash, in order to improve the blood flow rate in the catheter system.

Additionally, Applicant states that the beside the semicircular cross section shapes of catheter, other configurations may be used without departing from the spirit of the invention, such as, for example, oval, circular, elliptical, square...., see para [0032] of Specification. Therefore, one skill in the art would recognize that the circular cross section shape in Sisley can be modified in any shapes such as semicircular... is design choice.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley in view of Ash and further in view of Cazal (US 5,800,414).

Sisley in view of Ash discloses the invention substantially as claimed. Sisley discloses that the 2 catheters 12 and 14 are attached by 18a, see Fig. 3. However, Sisley does not clearly mention that the catheters 12 and 14 are attached by adhesive.

Cazal discloses a similar device, in which the first and second catheters are splittably joined to each other by adhesive 14 or 20. It is noted that, the adhesive 14 or 20 is capable of being splitted if using sufficient force to tear it.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Sisely in view of Ash, with an adhesive, as taught by Cazal, if one wished to easily join the two catheters.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 3763

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/974,267.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of instant claims are fully disclosed and covered by the claims in the copending application claims.

As noted that, claims 1-37 does not include the hub or an initially separate hub. However, the Applicant admitted that the hub 150 may be omitted is common sense or well-known in the art (see para 0036 of Specification or para 0050 of Application 10/974267). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to the releasable hub, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 34-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

Art Unit: 3763

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/
Examiner, Art Unit 3763